UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

KEITH ALOI, Plaintiff, v. ALEX M. AZAR II, in his official capacity as Secretary of Health and Human Services,[1] Defendant.	C.A. No. 17-420-JJM-LDA

MEMORANDUM AND ORDER

JOHN J. MCCONNELL, JR., United States District Judge.

I. INTRODUCTION

The issue in this appeal is whether the Medicare Appeals Council, was correct to overturn the decision of the Administrative Law Judge ("ALJ") giving Plaintiff Keith Aloi coverage for the medication dronabinol under the Medicare prescription drug plan (Part D).

Before the Court are two motions: (1) Plaintiff Keith Aloi's Motion to Reverse the Decision of the Medicare Appeals Council (ECF No. 17); and (2) Defendant Alex Azar, Secretary of the U.S. Department of Health and Human Services' Motion for

[1] This Court substitutes Alex M. Azar, II as the Defendant in his official capacity as U.S. Secretary of Health and Human Services, who succeeded Thomas E. Price who resigned from that position. *See* Fed. R. Civ. P. Rule 25(d) ("An action does not abate when a public officer who is a party in an official capacity dies, resigns, or otherwise ceases to hold office while the action is pending. The officer's successor is automatically substituted as a party. Later proceedings should be in the substituted party's name . . .")

Judgment on the Pleadings. ECF No. 18. The Court also received Mr. Aloi's memo (ECF No. 21) supporting his objection to the government's motion. Both sides have agreed that the Court should decide this case on these papers.

II. STANDARD OF REVIEW

Judicial review of a final decision of the Secretary under the Medicare Act is authorized by 42 U.S.C. § 1395w-104(h)(1) and governed by 42 U.S.C. § 405(g), the same statutory framework that provides the standard for judicial review of Social Security Disability benefit determinations. *See Walker v. Berryhill*, 857 F.3d 1, 3 (1st Cir. 2017). On review, a court "ha[s] the power to enter . . . a judgment affirming, modifying or reversing the decision of the [Secretary]." 42 U.S.C. § 405(g). The Court's review is to be based on the pleadings and the administrative record; and the Court should uphold the Secretary's decision if it was supported by substantial evidence. *See, e.g.,, Richardson v. Perales*, 402 U.S. 389, 401 (1971).

III. PROCEDURAL AND FACTUAL BACKGROUND

Mr. Aloi's treating physician, Dr. Barry Wall, prescribed dronabinol in May 2012 for the treatment of Mr. Aloi's symptoms from schizoaffective disorder and generalized anxiety disorder, finding that "adding dronabinol to [Mr. Aloi's] anti-psychotic medications help him with his sleep and affect his mood, and also helps him think more clearly to be more functional during the day." In October 2016, Mr. Aloi enrolled in Blue Medicare Rx (the "Plan") a Medicare Part D Prescription Drug Plan. Mr. Aloi requested pre-authorization for coverage of his dronabinol prescription, which the Plan denied. Mr. Aloi requested redetermination, which the Plan again

denied. Mr. Aloi then requested reconsideration by an Independent Review Entity ("IRE"). The IRE upheld the denial because Mr. Aloi's use of dronabinol was not covered because it was off-label; it held that "[t]he Medicare-approved compendia[2] do not contain any citations to support the use of this drug for [schizoaffective disorder and generalized anxiety disorder]." Mr. Aloi appealed the IRE's denial, and requested a hearing with an Administrative Law Judge.

Relying on the AHFS-DI in the compendium, the ALJ issued a decision concluding that Mr. Aloi's use of dronabinol constituted a "medically accepted indication" and ordered coverage. The IRE did not participate in the ALJ hearing, but later requested that the Medicare Appeals Council ("MAC") review the ALJ's decision. The MAC's review is limited to any errors of procedure or errors of law when the government did not participate in the ALJ's evidentiary hearing. 42 C.F.R. 423.2110 (c)(2), provides:

> "Referral by CMS or the IRE when CMS or the IRE did not participate or request to participate in the OMHA [Office of Medicare Hearings and Appeals] proceedings. The Council will accept review if the decision or dismissal contains an error of law material to the outcome of the case or presents a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review, the Council will limit its consideration of the ALJ's or attorney adjudicator's action to those exceptions raised by CMS or the IRE."

When reviewing an ALJ decision, the MAC should consider the evidence "contained in the record of the proceedings before the ALJ" and new evidence must relate to the

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[2] The approved compendia are (1) the American Hospital Formulary Service Drug Information (AHFS-DI); (2) the United States Pharmacopeia-Drug Information, or its successor publications; and (3) the DRUGDEX Information System for non-anticancer Part D drugs. 42 U.S.C. § 1396r-8(g)(1)(B)(i).

period before the coverage determination that led to the appeal. 42 CFR 423.2122(a)(1).

In its appeal to the MAC, the IRE asserted that the ALJ committed an error of law because the ALJ relied on an outdated version of the AHFS-DI (2014). Mr. Aloi opposed the IRE's appeal to the MAC. He argued that the current 2017 version of the AHFS-DI contains language much like the 2014 version and so the use of the earlier version was appropriate. Moreover, Mr. Aloi argued that to qualify as a "medically accepted indication," there is no requirement "that the compendia explicitly recommend use of the medication for a specific diagnosis," only that the use must be "supported by a citation in the compendia." The current version of the AHFS-DI supports the use of dronabinol for schizoaffective disorder or generalized anxiety disorder, stating, "'[d]ronabinol also demonstrates reversible effects on appetite, mood, cognition, memory, and perception . . . subject to great interpatient variability.'"

The MAC determined that "whether an ALJ applied the correct authorities is a legal error" material to the case and reversed the ALJ's decision. It denied coverage, agreeing with the IRE that the ALJ erred as a matter of law by relying on an outdated version of the [AHFS-DI] compendium. The MAC found that the ALJ "should have referenced the version of the AHFS-DI compendium in effect at the time of the review," concluding that the Plan did not have to pay for dronabinol "applying the current versions of the Medicare-approved compendia . . . [because it was not

prescribed] for a medically accepted indication and does not meet the definition of a Part D drug."

The MAC ruled that although the 2017 AHFS-DI states that dronabinol "has reversible effects on appetite, mood, cognition, memory, and perception," it reasoned this this does not amount to a "medically accepted indication" because it does not refer to "the diagnosis or condition" for which the drug is prescribed. Instead, the entry language relates to the effects of the drug on an individual, a distinct category in the particular compendium entry. The MAC determined that a "statement of the effects of a drug does not equate to a citation supporting the use of the drug for a medically accepted indication to treat a specific diagnosis or condition." Thus, the MAC found that Mr. Aloi's use of dronabinol was not covered.

IV. DISCUSSION

Section 1927(k)(6) of the Social Security Act, the applicable statute governing this case defines medically accepted indication as:

> any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.] or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section.

42 U.S.C. § 1396r-8(k)(6). Approval of a drug for a particular patient therefore hinges on either of two findings: (1) that the Federal Food, Drug, and Cosmetic Act approves the drug; or (2) the use is supported by one of more citations from an approved compendium. *See* note 2. The Court turns its focus on the second factor as both

parties agree that it is the relevant factor in analyzing Mr. Aloi's request for coverage for dronabinol.

Our analysis begins at the ALJ stage. Mr. Aloi's treating physician, Dr. Wall testified that the 2014 AHFS compendia supports the determination that Mr. Aloi's use of dronabinol is medically accepted because it "cites varying psychotic effects of dronabinol," and "the listing of those facts to be relevant to and support the use of the drug." He identified that the AHFS 2014 edition provides "somnolence and effects on mood, cognition and memory exhibit considerable interpatient variability." *See* 2014 AHFS at p. 2998. There was no evidence presented to the contrary and the Secretary did not attend the ALJ hearing. The ALJ found that

> there is at least one citation in the Medicare-approved compendia to support [Mr. Aloi's] use of the requested drug. The record reflects [Mr. Aloi] has diagnoses of schizoaffective disorder and generalized anxiety disorder. The American Hospital Formulary Service 2014 pharmacopeia compendia cites varying psychiatric effects of the medication that evidence [Mr. Aloi's] use is supported by the citation in the compendia. As the American Hospital Formulary Service 2014 pharmacopeia cites, somnolence effects on mood, cognition and memory can exhibit considerable inter-patient variability. The record indicates that that was exactly the type of benefit that has bene helpful for [Mr. Aloi].

Based on that uncontroverted testimony, the ALJ found that one or more citations in the compendia supported the use of the drug dronabinol as prescribed to the Mr. Aloi.

The MAC based its decision that the ALJ committed an error of law on the fact that the ALJ used the 2014 version of the AHFS-DI. A material error of law has been found when the ALJ abuses his discretion during the hearing or ignores a material factor that deserves significant weight. *United States ex rel. Jones v. Brigham &*

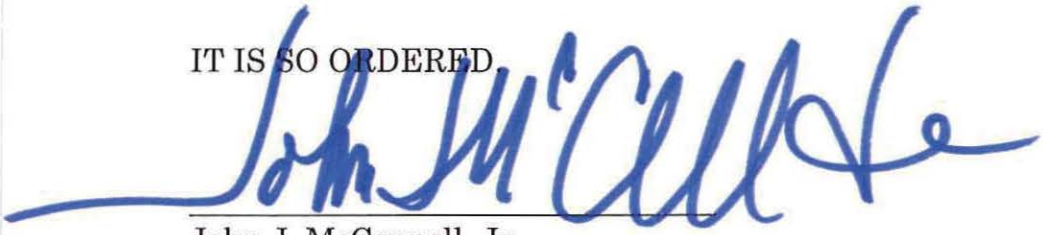
Women's Hosp., 678 F.3d 72, 83 (1st Cir. 2012). The Court finds that the MAC's finding is neither factually nor legally correct. At the hearing, the Secretary conceded that the language in the early version on which the ALJ and treating physician relied, was "substantially similar" to the current 2017 version. Indeed, both editions refer to the effects of dronabinol on mood, cognition, and memory, precisely the type of benefit that Dr. Wall and the ALJ found that Mr. Aloi would get from the medication.

But even if there were a substantial difference between the two versions, the ALJ's finding would not constitute an error of law. A material error of law "is not demonstrated by the disappointment of the losing party. It is the 'wholesale disregard, misapplication, or failure to recognize controlling precedent.'" *Oto v. Metro. Life Ins. Co.*, 224 F.3d 601, 606 (7th Cir. 2000) (quoting *Sedrak v. Callahan*, 987 F. Supp. 1063, 1069 (N.D. Ill. 1997)). The ALJ did not disregard controlling precedent. He found credible the uncontroverted testimony of the treating physician who relied on approved compendia materially similar to the current version. Because the facts presented to the ALJ established that the use of dronabinol as prescribed to Mr. Aloi was supported by a citation to the relevant compendia, there was no error of law and the MAC inappropriately reversed the ALJ decision.

V. CONCLUSION

The Court thus GRANTS, Mr. Aloi's Motion to Reverse (ECF No. 17), DENIES the government's Motion for Judgment on the Pleadings (ECF No. 18), and ENTERS JUDGMENT for Plaintiff, plus costs and attorney's fees.

IT IS SO ORDERED.



John J. McConnell, Jr.
United States District Judge

October 5, 2018